

# PART 1 of 3

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

**IN RE PRAECIS PHARMACEUTICALS, INC.  
SECURITIES LITIGATION**

Civil Action No. 1:04-cv-12581-GAO

**CONSOLIDATED AMENDED  
CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

Lead Plaintiffs, Kellie Seringer, the City of Dearborn Heights Police and Fire Retirement System, George Ladikos and Edward G. Bourne (collectively, "Lead Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, allege upon personal knowledge as to themselves and their own acts, and as to all other matters, based upon an investigation made by their attorneys that included, among other things: (i) review and analysis of the public filings of Praecis Pharmaceuticals, Inc. ("Praecis" or the "Company"), including its filings with the Securities and Exchange Commission ("SEC"); (ii) review and analysis of the statements of the Food and Drug Administration ("FDA"); (iii) interviews with former employees of Praecis; (iv) review and analysis of certain internal Praecis documents, and (v) review and analysis of news articles, press releases, and analyst reports by or relating to Praecis.

Based upon the evidence already developed, Lead Plaintiffs believe that further substantial evidentiary support will exist for the allegations in this Consolidated Amended Class Action Complaint after a reasonable opportunity for discovery. Most of the facts supporting the allegations set forth herein are known only to the defendants or are exclusively within their custody and/or control.

## NATURE OF THE ACTION

1. This is a federal class action on behalf of persons who purchased or otherwise acquired the securities of Praecis Pharmaceuticals Inc. (“Praecis” or the “Company”) between November 25, 2003 and December 6, 2004, inclusive (the “Class Period”), seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Lead Plaintiffs allege that during the Class Period the named defendants as identified below knowingly, or with deliberately reckless ignorance, made false and misleading statements regarding Praecis’s “lead product,” Plenaxis, which is among a group of medicines called gonadotropin-releasing hormone antagonists that are designed to lower levels of the male hormone testosterone -- a key factor in most prostate cancer growth. The Food & Drug Administration (“FDA”) approved Plenaxis for sale on November 25, 2003, the first day of the Class Period. The FDA, however, imposed severe restrictions upon the sale of Plenaxis, including a “black box” warning label and the imposition of a Risk Management Program (“RMP”).<sup>1</sup> In addition, the FDA narrowly defined the types of patients to whom Plenaxis could be prescribed: only those patients who can not tolerate other hormone therapies *and* who have refused surgical castration – at best 5 percent to 10 percent of prostate cancer patients. The FDA imposed the restrictions because the

---

<sup>1</sup> “Black box” labels are “designed to highlight special problems, particularly those that are serious, and to give health care professionals a clear understanding of a potential medical complication associated with a drug.” <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01325.html>. A “black box” warning label is the most serious FDA warning for prescription medication labels, and is the last step before the FDA pulls the drug from the market. See: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=34>

A Risk Management Program is a “strategic safety program designed to decrease product risk by using one or more intervention tools beyond the package insert.” *FDA Concept Paper: Risk Management Programs*. Among the FDA’s recommended tools are: Specialized educational materials for doctors and patients; processes for forms to increase compliance with reduced-risk prescribing; and systems that modify conventional prescribing, and use of the product to minimize specific risks. *Id.*

approval studies demonstrated that Plenaxis users were at risk of life-threatening allergic reactions, including a precipitous drop in blood pressure. Indeed as part of the RMP, the FDA required that any patient who received Plenaxis be monitored by the physician for at least 30 minutes after receiving a Plenaxis injection.

3. At the beginning of the Class Period, Defendants substantially inflated the potential market for Plenaxis and sales forecasts in light of known facts – *i.e.* that (i) the primary purchasers, urologists, lacked the necessary distribution system to purchase Plenaxis; (ii) Praecis's pricing structure offered the target physicians (urologists) little opportunity to profit while at the same time substantially increased the urologists' risk of loss; (iii) the 30 minute monitoring period further decreased urologists' profits, if any, from Plenaxis because during that time a consultation room could not be used by another patient; (iv) Plenaxis's "black box" warning label also significantly increased urologists treatment and malpractice concerns, particularly in light of the fact that the existing competing medications used to treat prostate cancer bore no such warning labels, had been effectively prescribed for fifteen years, and could be prescribed to a much larger group of prostate cancer patients. Despite these known facts, Defendants stated that the market for Plenaxis was \$160 million to \$360 million. Based on this rosy forecast, the Company insisted that its first-year sales would be approximately \$10-\$20 million. Based on the November 26, 2003 approval announcement and forecasts, as well as the January 2004 first-year sales forecasts, Praecis's stock price rose over 14% in the days that followed.

4. Moreover, as the Class Period continued, Defendants continued to issue rosy forecasts and downplayed the risks of Plenaxis, even as more and more facts came to light that directly contradicted those forecasts. Indeed, despite the significant rejection of Plenaxis by its target market,

Defendants asserted that low sales would be cured by the marketing staff using a more focused message.

5. As Plaintiffs have discovered, that more “focused message” was a direct instruction from Defendants to the Plenaxis sales force to bypass the limited indications (i.e., the FDA’s strict restrictions on the type of prostate cancer patients who could be treated with Plenaxis) and minimize the potentially fatal side-effects of Plenaxis in order to increase sales.

6. Moreover, Defendants’ desperation to increase sales led them to engage in “management by intimidation,” threatening the sales representatives with termination if sales did not increase. This management model led to an undisclosed collapse of the morale of the sales force. Despite Defendants’ statements to the contrary, by the second half of 2004, most, if not all of the sales people experienced in selling limited indication medications were leaving the Company. Moreover, Praecis had gained such a bad reputation among pharmaceutical sales representatives that it could not attract experienced sales representatives and was replacing its experienced staff with wholly unsuitable and inexperienced sales people.

7. In June 2004, for the first time, the Company backed off its initial sales forecasts, but continued to state that its “experienced” sales force would be applying a new marketing message and that the Company was on line to be profitable in 2006.

8. Despite these efforts, Plenaxis’ sales continued to plummet, and on December 6, 2004, the last day of the Class Period, the Company withdrew all guidance on the sales and revenues from Plenaxis and stated that it planned to re-launch Plenaxis under a new sales model.

9. This news shocked the market. Shares of Praecis fell \$.56 per share, or 25.8 percent on December 6, 2004, to close at \$1.61 per share.

10. Since the close of the Class Period, Praecis has confirmed that there is essentially no sustainable market for Plenaxis in the United States. On May 20, 2005, Praecis announced that it was firing 60 percent of its 182-person work force and halting U.S. promotion of Plenaxis except to provide the drug to patients already on the therapy.

11. As a result of defendants' misrepresentations and material omissions the price of Praecis's stock was artificially inflated throughout the Class Period, when Lead Plaintiffs and members of the Class purchased shares of that stock. Right after the end of the Class Period, when the truth was finally at least partially disclosed, the stock plummeted by more than 25%, the minimum amount by which Lead Plaintiff and the Class members were damaged.

### **JURISDICTION AND VENUE**

12. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

13. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

14. Venue is proper in this Judicial District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this Judicial District. Additionally, the Company maintains a principal executive office in this Judicial District.

15. In connection with the acts, conduct and other wrongs alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,

including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

### **PARTIES**

16. Lead Plaintiff, Kellie Seringer, as set forth in the certification previously filed in this litigation and incorporated by reference herein, purchased Praecis securities during the Class Period and has been damaged thereby.

17. Lead Plaintiff, the City of Dearborn Heights Police and Fire Retirement System, as set forth in the certification previously filed in this litigation and incorporated by reference herein, purchased Praecis securities during the Class Period and has been damaged thereby.

18. Lead Plaintiff, George Ladikos, as set forth in the certification previously filed in this litigation and incorporated by reference herein, purchased Praecis securities during the Class Period and has been damaged thereby.

19. Lead Plaintiff, Edward G. Bourne, as set forth in the certification previously filed in this litigation and incorporated by reference herein, purchased Praecis securities during the Class Period and has been damaged thereby.

20. By an Order dated April 13, 2005, the Court appointed Kellie Seringer, the City of Dearborn Heights Police and Fire Retirement System, George Ladikos and Edward G. Bourne as Lead Plaintiffs.

21. Defendant Praecis is a Delaware corporation that maintains its principal place of business within this judicial district at 830 Winter Street, Waltham, MA 02451.

22. Defendant Malcom Geffer was, at all relevant times, the Company's Chairman and Chief Executive Officer.

23. Defendant William K. Heiden was, until his resignation on September 7, 2004, the Company's President and Chief Operating Officer.

24. Defendant Kevin F. McLaughlin was, until his appointment on September 7, 2004, as the Company's President and Chief Operating Officer, the Company's Vice President and Chief Financial Officer.

25. Defendant Edward C. English was, since his appointment on September 7, 2004, the Company's Chief Financial Officer and Treasurer of the Company.

26. Defendants Geftter, Heiden, McLaughlin, and English are collectively referred to hereinafter as the "Individual Defendants."

#### NON-PARTY SOURCES

27. As expressly noted in specific instances, *infra*, Lead Plaintiff relies for certain allegations upon a number of former Praecis employees.

28. Confidential Source No. 1 ("CS No. 1") was a former Oncology Specialist (*i.e.* sales representative), in Praecis's South-East region from early 2004 until late 2004, when he or she was terminated because he or she refused to sell Plenaxis outside of the FDA approved indications.<sup>2</sup> CS No. 1 had over twenty years experience as a pharmaceutical sales representative, in particular selling cancer related medication, with some of the top pharmaceutical companies in the world. At Praecis, CS No. 1 was responsible for visiting urologists and promoting Plenaxis. CS No. 1 provided corroborated descriptions of Praecis management directing sales representatives to increase Plenaxis

---

<sup>2</sup> Praecis had five sales regions for Plenaxis. The South Eastern territory included Texas, Oklahoma, Louisiana, Mississippi, Alabama, and Florida. The Southern territory included Georgia, Washington D.C., the Carolinas, Virginia, Maryland, Tennessee and Ohio. The North Eastern territory included New York, and New England. There were also a mid-West or Central Region and a Western Region. Each Region has at least one Regional Manger responsible for all sales representatives.



sales by using questionable product messaging. He or he also provided details about the SPIDER sales tracking system, the PLenaxis(TM) User Safety Program ("PLUS")<sup>3</sup> training program, how Plenaxis is administered, and factors that should have been taken into consideration by the Individual Defendants, and despite his or her efforts, which the Individual Defendants ignored.

29. Confidential Source No. 2 ("CS No. 2") was a former Oncology Specialist (*i.e.* sales representative), in Praecis's North-East region from mid 2004 until late 2004, when he or she was laid-off with a large number of other sales representatives. Prior to joining Praecis, CS No. 2 had nearly fifteen years experience selling cancer related medications for two of the largest pharmaceutical companies. CS No. 2 provided background information on Praecis sales and also described troubling directions from Praecis management. CS No. 2 stated that he or she was relieved when he or she was laid off by Praecis. CS No. 2 stated that his or her association with Plenaxis affected him or her both personally and professionally. Indeed, he or she stated that his or her relationships with urologists were so damaged by the Plenaxis sales tactics, he or she has abandoned future employment opportunities in that field.

30. Confidential Source No. 3 ("CS No. 3") was a former Praecis Oncology Specialist in Praecis's Western Region from early 2004 until mid 2004. CS No. 3 described Praecis sales training, weak sales for Plenaxis, aggressive sales tactics, sales forecast revision, and explained the small market size for Plenaxis. As part of his or her duties, CS No. 3 visited physicians and promoted Plenaxis.

31. Confidential Source No. 4 ("CS No. 4") was a former Senior Oncology Specialist in Praecis's South-East Region. He or she was employed at Praecis from January 2004 until May 2005.

---

<sup>3</sup> PLUS was Praecis's name for the RMP imposed by the FDA.

CS No. 4 provided information regarding Praecis's Medicare reimbursement issues and corroborated statements made by the other Confidential Sources. As part of his or her duties, CS No. 4 visited physicians and promoted Plenaxis. CS No. 4 was a top ranked sales representative in his or her region and nationwide.

32. Confidential Source No. 5 ("CS No. 5") was a former Oncology Specialist in Praecis's Central Region. He or she worked at Praecis from early 2004 until mid 2004. CS No. 5 provided information regarding the methods Praecis used to improve weak Plenaxis sales, in particular, by using misleading terminology. CS No. 5 also provided information regarding the declining sales forecasts, Medicare restructuring, improper sales training and sales tactics, as well as details about the computer system used by sales representatives. By the time of his or her employment with Praecis, CS No. 5 had seven years of experience selling "difficult to sell" medications.

33. Confidential Source No. 6 ("CS No. 6") was a former Oncology Specialist, working in Praecis' Southern Region. He or she worked at Praecis from February 2004 until October 2004, and was one of the Company's top sales representatives in the first quarter of 2004. CS No. 6 confirmed statements made by witnesses CS No. 1 and CS No. 5 about misleading Plenaxis product messaging. CS No. 6 also described weak Plenaxis sales numbers and the pressure applied to Plenaxis sales representatives. As part of his or her duties, CS No. 6 visited physicians and promoted Plenaxis.

34. Confidential Source No. 7 CS No. 7 ("CS No. 7") was a former Regional Manager for Praecis. CS No. 7 worked for Praecis from late 2003 until late 2004. CS No. 7 reported directly to the National Sales Director, Jeffery Sherman ("Sherman"). CS No. 7 coordinated all sales

representatives in his or her region. CS No. 7 provided Plaintiffs with details about weak sales for Plenaxis and Praecis's pricing policy which negatively impacted Plenaxis sales. CS No. 7 is a well experienced pharmaceutical sales manager, with well over twenty years experience with some of the best known pharmaceutical companies.

35. Confidential Source No. 8 ("CS No. 8") was a former Praecis staff accountant who worked at Praecis's Massachusetts headquarters from late 2003 until spring 2004. Among his or her duties as a staff accountant, CS No. 8 performed monthly closing of the general ledger, reconciliation of balance sheet accounts for monthly analysis, review and analysis of contract agreements and their subsequent renewal on a quarterly basis, and gave assistance to the pricing specialist with the charge back program. CS No. 8 provided collaborative information regarding Plenaxis' dismal sales performance during the Class Period, and the availability of that information to the Defendants.

#### **CLASS ACTION ALLEGATIONS**

36. Lead Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the securities of Praecis between November 25, 2003 and December 6, 2004, inclusive (the "Class Period") and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

37. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Praecis' securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can

only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Praecis or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

38. Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

39. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

40. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Praecis; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

41. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the

damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

42. In its form 10-K filed with the SEC, Praecis describes its self as a “biopharmaceutical company focused on the discovery and development of therapies to address unmet medical needs.” In its press releases, and conferences calls with investors and analysts, the Company described Plenaxis as its “leading product” and touted its approval by the FDA, the first such approval Praecis received. Plenaxis (abarelix for injectable suspension) is a treatment for advanced symptomatic prostate cancer in men. Plenaxis is not a cure for prostate cancer, but merely a palliative, designed to lessen some of the disease’s painful symptoms. As noted above (¶ 2); the FDA imposed severe marketing restrictions on Plenaxis as well as significantly limiting the number and type prostate cancer sufferers who could take the drug.

43. Despite these severe marketing limitations, one day after the FDA approval was announced, on November 26, 2003, Defendant Gefter appeared on CNBC to tout Plenaxis’s approval. In that appearance, Defendant Gefter stated in response to a question that set forth the analysts’ estimates of the market for Plenaxis as between \$50 and \$200 million:

the current market for hormonal therapy is actually \$1.2 billion in the United States alone. And that represents the combined hormonal therapies that are available for prostate cancer patients. And we've estimated that our drug would be applicable to treat a large segment of that population. **And we have estimated somewhere north of 15 to 20 to 30 percent of that size market would be available to patients taking our drug.**

44. In other words, Defendant Geftter was setting forth a sales estimate between \$180 million to \$360 million per year. However, this estimate was wholly illusory and ignored a multitude of facts that had a direct impact on Praecis's ability to sell Plenaxis and of which the Defendants knew or should have known.

45. Indeed, based on the statements set forth by the Confidential Sources, Defendant Geftter's November 26, 2003, forecast had no reasonable basis at the time it was made, and there were specific undisclosed facts known to Geftter which tended to seriously undermine the accuracy of the forecast. As set forth below, Geftter and the other Defendants knew or should have known that the market for Plenaxis was substantially smaller than that stated in Geftter's forecast market, that the low-profit margin for urologists further decreased the market, and the need to establish a distribution network for urologists would add significant costs and would add downward pressure on sales. Moreover, the combination of Plenaxis' "black box" warning label and the FDA required RMP would have further deleterious effects on the sales of Plenaxis. Particularly, where as here, the urologists can offer other treatments, the prescribing of Plenaxis would have substantially increased the urologists' medical malpractice risks while the RMP's required 30 minutes of observation would decrease the number of patients the urologist could see.

46. The small nature of the market was demonstrated by a 2002 study by the American Urologic Association ("AUA"). The Study found that 55.6% of the prostate cancer patients had mild symptoms, 37.1% had intermediate symptoms, and only 7.3% had severe symptoms. Here, Plenaxis could only be sold to those patients who had "severe" symptoms and who "opted" against surgical castration – a much smaller sub group of the "severe" group.

47. The small nature of the market for Plenaxis was confirmed by the Confidential Sources. For example, CS No. 3 stated that from the date of its approval, Plenaxis was suitable as a palliative for patients with severe, advanced prostate cancer.<sup>4</sup> According to CS No. 3, because Plenaxis could only be used within narrow application, urologists expected to see no more than three patients a year that would need Plenaxis. CS No. 3's analysis was supported by CS No. 7, a person with well over twenty-years of experience selling pharmaceuticals. CS No. 7 had seen Defendant Gefters' CNBC interview, and during this interview, stated that Plenaxis would be a tough sell and that at best, Plenaxis had a developed market potential of \$10 to \$20 million per year.

48. In addition to the small market, the "black box" warning label would have a negative impact on the market for Plenaxis. CS No.3 stated that it was well known within the pharmaceutical industry that a black box warning label causes significant sales difficulties. CS No.3, who had sold "black box" warning label drugs in a previous employment, noted the "black box" warning label's negative effects on sales increased significantly if there was competition from a drug that bore no such label.

49. CS No. 1 agreed with both of CS No. 3's assessments of the effect of the "black box" warning label and further identified a drug that directly competed with Plenaxis and was not burdened by a "black box" warning label.

50. According to CS No. 1, at the time Plenaxis was approved, physicians had already been prescribing Lupron for 15 years for the same symptoms that Plenaxis claimed to treat. Moreover, Lupron did not have a "black box" warning label and the FDA had approved it for

---

<sup>4</sup> Palliative treatments ease terminal patient symptoms but do not provide cures.

broadier indications than Plenaxis (*i.e.* Lupron could be administered to more prostate cancer patients than Plenaxis). Moreover, Lupron was highly profitable for the urologists.

51. Lupron did have one drawback -- patients taking Lupron could have “testosterone flares,” which can negate the palliative effects of the treatment. (Indeed, Praecis harped on the testosterone reducing effect of Plenaxis as benefit in contrast to Lupron as the core basis for its sales potential.) Patients taking Lupron, however, could also take Casodex to mitigate the testosterone flares. Although expensive, Casodex was found to mitigate Lupron’s testosterone flares after only two weeks of doses. Moreover, urologists did not face any billing risks with Casodex because patients purchased Casodex at pharmacies.

52. In addition to the high profit/low side-effect and non-payment risk of prescribing a course of treatment with Lupron and Casodex rather than Plenaxis, was the fact that neither Lupron nor Casodex had “black box” warning labels that had a negative impact on potential sales. It is reasonable to infer that urologists would weigh the comparative health risks to patients and malpractice risks to themselves of choosing a new, high risk treatment such as Plenaxis against the lower health and medical malpractice risks of prescribing Lupron/Casodex -- a well-established course of treatment and choose to continue prescribing Lupron/Casodex over Plenaxis.

53. In addition to the effect of the “black box” warning label, Praecis’s pricing structure did not provide a significant enough profit motive for the urologists to prescribe the drug. CS No. 1 stated that he or she informed management the pricing structure for Plenaxis was significantly flawed. CS No. 1 stated that despite discounts offered to urologists for large amounts of Plenaxis, the urologists faced a substantial risk of loss unless they had enough patients and could receive



discounts. According to CS No. 1, urologists risked a loss of approximately \$40 dollars per prescription; CS No. 4 estimated the risk of loss as approximately \$120 per dose.

54. The initial wholesale price (around \$780 dollars), the discounted price (around \$700 per vial for purchases of around 18 vials), and the Medicare reimbursement (around \$720 dollars) meant that urologists would need five or more Plenaxis patients to become profitable. CS No. 4 believed that the best profit a urologist could obtain was approximately \$10 per dose. Indeed, because doctors could obtain Plenaxis within 24-48 hours, they had no medical reason to stock up on Plenaxis for a non existent patient base.

55. According to CS No. 1, urologists were very reluctant to begin prescribing a new (its J-code had not yet assigned), risky (the FDA mandated PLUS program), and unprofitable drug like Plenaxis. Praecis management ignored these facts and retained their Plenaxis pricing structure.

56. Moreover, as noted above, CS No. 1 stated that urologists were already prescribing Lupron at a profit. Moreover, Lupron also offered patients an easier choice – it was taken every six months rather than Plenaxis's frequent office visits. CS No. 1 believes Praecis management mistakenly used the combined price of Lupron and Casodex, ignoring the less frequent use of Lupron and the short-term use of Casodex, as a guideline for their pricing of Plenaxis.

57. In addition to impact of the "black box" warning label, the PLUS RMP imposed by the FDA would also negatively affect Plenaxis sales. Under Plus, the Praecis sales representatives, called Oncology Specialists, trained the urologists in the use of Plenaxis. Praecis Oncology Specialists distributed two forms and some pamphlets to physicians and explained the proper method of administering Plenaxis and its side effect profile. Under the PLUS program, the urologists were required to keep the patient under supervision in an examination room for one half hour after

receiving an injection of Plenaxis. After receiving this information, physicians were required to sign a PLUS form acknowledging that they had received and understood the training for Plenaxis.

58. Furthermore, the PLUS program required, as CS No. 1 stated, a second form and product pamphlets to be given to patients. Patients were required to sign the second form to confirm that they understood the Plenaxis information that they had received – in particular that they understood the significant health risks associated with taking Plenaxis.

59. According to CS No. 1, the PLUS program inhibited Plenaxis sales. Urologists were cautious about prescribing Plenaxis because of the extensive risks identified in the training form they had signed. Urologists were concerned about the hypotension that Plenaxis could cause. Indeed, hypotension (abnormally low blood pressure) could be fatal.

60. Moreover, the frequent patient visits required by Plenaxis also caused concern among the urologists. According to CS No.1, Plenaxis was administered via intramuscular (IM) injections into the patient's buttocks. The first Plenaxis injection would be followed by a second injection fifteen days after the first injection, a third injection twenty-nine days after the first injection, and then an injection every four weeks. Because Plenaxis was a palliative treatment (it would not cure the condition), the injections schedule went on indefinitely. According to CS No. 1, these frequent visits did not compare well with the one dose every six months that a patient would take in a course of Lupron.

#### **THE SALES TRAINING AND RELEASE**

61. On January 30, 2004, Defendants issued new sale projections for the coming year -- \$10-\$20 million. While that is significantly less than projected in November 2003, the projections

suffer from a similar lack of a reasonable basis and were made in direct contradiction to the known facts.

62. Indeed, from the training sessions attended by the Confidential Sources, it is clear that the Defendants knew that the factors identified in ¶¶ 45-60 were going to have a significant impact on sales. As described below, it was at these training sessions that Jeff Sherman first insisted that the sales representatives down play the seriousness of the health risk and suggest the drug for use for milder cases, beyond the strict limitations of the FDA approved indications.

63. CS No. 3 and CS No. 5 stated that Jennifer Mills conducted the sales training at the Praecis home office. CS No. 3 stated that most of the training was oral and the few written materials were “letter of the law stuff.”

64. Both CS No. 3 and CS No. 5 stated that during the course of their training Sherman and Marc Garnick, Praecis’s Chief Medical Officer, attended the sessions and conducted certain parts of the training. Sherman and Garnick would join the group and discuss Plenaxis. Garnick would discuss the science behind Plenaxis. Sherman would discuss the Plenaxis market and describe aggressive sales techniques. CS No. 5 stated that Sherman discussed cost vs. wholesale price, margins, and reimbursements and suggested means for the sales representatives to assuage a urologist’s misgivings about profit and reimbursement. Sherman also told CS No. 5 and other sales representatives to try and convince physicians that prescribing Plenaxis would be more profitable than prescribing alternatives like Lupron. Sherman highlighted the greater number of office visits for Plenaxis patients during sales training and stated that because of the increased number of patient visits, physicians might see larger revenue from Plenaxis patients over time.

65. Both CS No. 3 and CS No. 5 agree that after Sherman would leave the room, Mills would correct any statements that encouraged bad practices. Mills would essentially say “the opposite of what Sherman had said.” CS No. 5 stated that Mills would correct Sherman’s statements by explaining what could and could not be said. Mills would caution the sales representatives to refrain from discussing those topics with physicians.

66. Because Sherman worked closely with Praecis management, and because Garnick was present when Sherman directed sales representatives to act improperly, CS No. 5 believed Praecis management, including the Individual Defendants, was fully aware of Sherman’s improper guidance. Moreover, as described below, Sherman continued to pressure sales staff to sell Plenaxis off indication.

67. The January 2004 forecast was also plainly inconsistent with the sales objectives given to the sales representatives in the training sessions. Prior to the release of Plenaxis, CS No. 1 was told by Sherman that each sales representative was expected to acquire ten patients each, between February 2004 and June 2004. Based on this requirement, there was no possible way for Praecis to meet its forecasts.

68. As CS No. 1 stated, there were forty Plenaxis sales representatives. Moreover, in the 4 months between February and June 2004 (assuming all the patients were acquired on February 1<sup>st</sup>, each patient would need six vials (3 in the first 45 days, with an additional vial every four weeks). Under that formula, a sales representative would sell only 60 vials (6 vials x 10 patients), or total sales force sales of 2,400 vials. With a price of \$700 per bottle, 2,400 vials represent gross sales of only \$1.68 million. In order just to reach the low end of the estimate, sales representatives would have to sell more than five times as much in the second half of the year.

69. When Praecis launched Plenaxis in March, 2004, it was a dismal failure. CS No.3 stated that for the first 60 days, urologists did not want to buy and did not want to stock Plenaxis. CS No. 2 stated that during sales visits some physicians would yell at him or her about the way Praecis was marketing Plenaxis. Physicians complained about the way Praecis tried to minimize the reactions that patients would experience. Some physicians complained that Plenaxis patients would “tie up examination rooms.”

70. CS No. 8 stated that orders from distributors were infrequent – only a few each week. Moreover, each distributor order was small, with only a few vials in each order.

71. Because initial sales of Plenaxis were so weak, Defendants began what CS No. 2 described as “management by intimidation.” Praecis management would attack the qualifications of the sales representatives, threaten to fire the sales representatives, and instructed sales representatives to “skirt[] the rules” in order to increase sales.

72. For example, CS No. 5 was instructed to identify patients for Plenaxis. CS No. 5 refused because that was the role of physicians. According to CS No. 5, identifying patients for Plenaxis would require sales representatives to have access to patient information that was protected by FDA and patient privacy guidelines. Management told CS No. 5 that his or her market for Plenaxis “failed” because he or she refused to identify patients. Although CS No. 5 transmitted his or her serious concerns to Human Resources about the unethical (and possibly illegal) request, he or she received no reply.

73. During the course of his or her employment at Praecis, CS No. 5 was troubled by Management’s lack of professionalism, intimidation tactics, and the “Jeckle and Hyde” work environment. In particular, CS No. 5 highlighted his or her Regional Manager’s unethical behavior –

behavior that was countenanced by Praecis. According to CS No. 5, when he or she and his or her Regional Manager visited customers together, the Regional Manager would engage in clearly inappropriate behavior -- including lying and confronting physicians in parking lots. The Regional Manager wanted CS No. 5 "to do whatever it took to make a pitch." CS No. 5 reported his or her concerns about his or her Regional Manager's unethical behavior to the Human Resources Department on multiple occasions. He or she also expressed such concerns in writing to the Board of Directors of Praecis.

74. Defendant Heiden contacted CS No. 5 by phone and informed him or her that the Board of Directors had reviewed his or her letter and determined that CS No. 5 was overreacting because he or she was uncomfortable with his or her Regional Manager's "style." CS No. 5 never received a response from Human Resources, nor was the Regional Manager ever disciplined.

75. CS No. 3 stated there was a lot of pressure to improve the weak sales numbers for Plenaxis. According to CS No. 3, Regional Managers were under significant pressure because they were not "moving product." CS No. 3 recalled that during weekly teleconferences, Regional Managers instructed sales representatives to "work the gray areas" of patient indications -- *i.e.* expand the patient base beyond the strict limitations imposed by the FDA.

76. According to CS No. 1, CS No. 3, and CS No. 5, Praecis allowed its Plenaxis customers to purchase one vial of Plenaxis and delay payment until the Plenaxis had been injected into a patient. However, the delayed payment plan had a significant draw back -- urologists could -- and did -- return Plenaxis.

77. CS No. 1 stated that the free return policy had a substantial problem --when physicians returned vials of Plenaxis, some distributors would charge physicians 25% of the cost of Plenaxis as

a charge back. Praecis sales representatives were unaware of these charge back policies until physicians called and complained. Understandably, physicians were upset by these surprise costs and blamed Praecis for failing to inform them of the charge backs on returns.

78. As described by CS No. 3, this program failed utterly. Using the delayed payment plan, a sales representative from Pittsburg had “pre-sold” a substantial amount of Plenaxis. However, within a short time, nearly all of the pre-sold Plenaxis was returned. According to CS No. 3, “management had a fit.” In the end, the Company received substantial returns, and the urologists were angry regarding the charge backs.

79. CS No. 7 stated that, in April or May 2004, Praecis instituted a new policy whereby sales representatives received \$100 dollars for each vial of Plenaxis sold directly with established payment terms and received nothing for vials sold with a delayed payment term. In order to make these sales attractive to urologists, every vial purchased was counted towards a cumulative total. If the cumulative sales total for a physician was large enough at the end of the year, the physician would receive rebates from Praecis. Because of the expense of stocking Plenaxis, rapid deliveries, and the rebate policy, urologists would order Plenaxis as needed.

80. Despite all of the above mentioned problems, the Individual Defendants reiterated the \$10 to \$20 million sales forecast in April 2004. It was not until May 24, 2004, that the Company first expressed that it could no longer confirm its forecasts and not until December 2004 that it repudiated those projections completely.

#### **PLENAXIS CHANGES TO AN “OFF-INDICATIONS” SALES MESSAGE**

81. Despite the Company’s May 24, 2004 statement that it would no longer confirm its sales forecasts, the Individual Defendants increased the pressures on the sales staff. CS No. 2, CS

No. 3 and CS No. 5 were told in early June of 2004 to “overstate the indications and understate the allergic reactions” in order to improve the weak sales numbers for Plenaxis.

82. In addition, Sherman informed both CS No. 5 and CS No. 3 to urge physicians to consider patients with “mild” AUA Symptom Scores (a score above 6-7) as candidates for Plenaxis. As noted above, the FDA limited Plenaxis to those patients with severe symptom scores (*i.e.* 20 or above). These instructions were clearly attempts to boost sales by selling off indication.

83. As described below, the Individual Defendants actively pursued the off-indication strategy at a national sales conference held at the Hyatt Regency in Cambridge, Massachusetts held on June 21-23, 2004. CS No. 2, CS No. 5 and CS No. 6 attended the conference. Defendants William Heiden, Malcom Geftter, and Kevin McLaughlin were all present. Sherman, the National Sales Manager, also attended.

84. CS No. 5 described the theme of the meeting as “let’s make it happen.” – *i.e.*, management’s attempt to reenergize the sales team because they were encountering market resistance and weak sales for Plenaxis.

85. CS No. 2, CS No. 5 and CS No. 6 each describe the conference similarly. There would be a general meeting about the state of affairs at the Company – “not good” -- and then the attendees would attend breakout sessions. An executive addressed each group of sales representatives at these breakout sessions. CS No. 6 stated that Sherman and defendant William K. Heiden went from room to room to visit each breakout session.

86. During the course of the breakout sessions, Individual Defendants introduced the new “sales message.” CS No. 2 attended a breakout out session in a room with about five tables. Four or five sales representatives sat at each table. CS No. 2 stated that there were two pieces of paper on



each table. The two documents were shared among the sales representatives at each table. One of the documents was a list of niche terms and the other was a list of substitute non-niche terms. Sales representatives were directed to use the substitute terms, terms that downplayed the seriousness of the original niche term, when promoting Plenaxis.

87. Based on the documents provided by the Confidential Sources, the messaging documents appeared as follows:

<b>NON - "NICHE" WORDS</b>  <b>[I.E. AVOID USING]</b>	<b>NON - "NICHE" WORDS</b>  <b>[I.E. USE INSTEAD OF "NICHE" WORDS]</b>
Advanced Ureteral Obstruction Bladder Neck Outlet Obstruction Metastatic Cord Compression Hypotension Syncope Severe Orchiectomy Neurologic Compromise Serious Waning Efficacy	Symptoms Associated with Their Prostate Cancer Urinary Symptoms "High Risk" For Developing Symptoms (i.e. vertebral involvement that could lead to symptoms) Hormone Responsive Prostate Cancer Mild Moderate Rapid/Immediate Bone Pain Rare Incidence of Allergic Reactions (Occurred early < 8 minutes) (Resolved Uneventfully) Dizziness Transient Drop in Blood Pressure Relief of Symptoms Testosterone Fluctuations

88. CS No. 6 also stated that during the breakout session in which the niche and non-niche term documents were presented, the sales representatives were asked to participate in role-playing exercises. During the role-playing exercises, sales representatives were directed to use non-niche phrases (like “urinary symptoms”) whenever they mistakenly used serious terms (like “bladder neck outlet obstruction”).

89. CS No. 5 stated that the new, “misleading” Plenaxis product messaging (*i.e.* the non-niche terms”) was management’s response to the weak sales of Plenaxis. He or she felt that the use of layman’s terms instead of medical terms to describe indications was intentional. He or she further felt that it was the enactment of Defendant Heiden’s stated goal of the meeting—“to influence physicians to use the replacement terms when speaking with patients.”

90. However, not all the experienced sales staff were prepared to sell Plenaxis “off-indication.” Indeed, CS No. 1 was fired when he or she refused to sell “off-indication,” and others left voluntarily.

### **THE SALES FORCE REVOLTS**

91. At the beginning of the Class Period, according to CS No. 1, Praecis was able to attract, “experienced, professional oncology specialists.” CS No 2 agreed with this assessment. However, because Praecis engaged in “management by intimidation” (CS No. 2 and No. 5) and created a “Jekyll and Hyde” work environment (CS No. 5), and because of the requests to use unethical sales practices, staff morale was extremely low. Within the first few months after the Plenaxis launch, Praecis lost most of its most experienced sales representatives.

92. CS No. 6 stated that Sherman wanted sales representatives to work long days. CS No. 6 described it as “management by intimidation.” Sherman would tell sales representatives, “We have

the budget. I want breakfast, lunch, and dinner.” That phrase implied working from 5:30AM until midnight. Sales representatives were told that if they did not sell 7 vials of Plenaxis by the end of the month they would be fired (which was usually an empty threat). CS No. 6 heard a rumor that, as quickly as six months into the launch of Plenaxis, Sherman had directed Regional Managers to fire their two worst sales representatives.

93. Indeed, the dismay and anger of the Praecis sales representatives can be seen in the virulent posts on the Café Pharma website.<sup>5</sup> A sampling of the posts follows.

94. One Café Pharma poster stated:

People came here to escape big pharma and got an anal company with a bean head National sales mgr now acheiving glory in special projects. RM's with no class and a drug that is sold off label. Reps were not afraid of the boxed warning because plenaxis is meant for the worst patients. Benefit out weighs risk when you are as bad as that. The minute we get in they go off label and extend the risky drug to patients that would have been fine on Lupron. How could any research get you that knowledge.

95. Another Café Pharma poster stated:

**It was exciting at first and then the RM's sucked the life out of it. If we had stayed on label and the RM's did not threaten at 10 weeks in the field, it probably would have worked. We had a chance to save it but MG [Defendant Gefter] and KL decide to waste everyones time and lie lie lie at the meeting. That meeting was all about the RM's and the fact that they are all still around speaks volumes about this company and the business savy of malcolm [Defendant Gefter] (double company failure) and kevin (nice innocent face full of lies) now the reps I speak with are happy when they see things go wrong and can't wait to leave and others itching to report the company to the FDA. One poster said that you reap what**

---

<sup>5</sup> Cafe Pharma describes itself as “a site for drug reps by drug reps. We hope you find a sense of community here--a place where you can meet with others in our industry and share your successes and struggles, etc. Here, you may learn which companies are hiring and firing; which companies you want to work for and which ones you don't. Often your fellow reps are a great source of ‘behind the scenes’ information.” <http://www.cafepharma.com/cafeaboutnew.asp>

you sow and this company and the RM's sowed the seeds of failure by intimidation and just plain terrible treatment that have brought us where we are today. If people are so full of anger that they have to talk about yoko's personal bad habits then I really do not blame them for doing it.

96. Within months of launch, Praecis experienced significant attrition of its sales staff. At that time, according to CS No 1, Praecis began to hire inexperienced primary care sales representatives into oncology specialist positions. These inexperienced sales representatives lacked the necessary skills to sell a “black box” warning labeled drug like Plenaxis. Indeed, Plenaxis’s second half 2004 sales fell precipitously.

### **THE DEATH KNELL FOR PLENAXIS**

97. In August of 2004, Praecis once again changed its pricing policy for Pleanxis and ended the rebate program. CS No. 7 stated that the change caused a significant number of urologists to complain (*i.e.* those who were building up toward the year end target) and sales plummeted. CS No. 7 further stated that the change in pricing policy and the elimination of the rebate program was the “death knell” for Plenaxis.

98. Plenaxis was never able to achieve significant or even moderate sales growth. CS No. 7 stated that by the end of 2004, sales were closer to \$1 million dollars. Moreover, even the top five sales representatives had low sales numbers. As CS No. 7 stated, even if all of the Praecis sales representatives had been able to match the top sales representatives, Praecis would still fall short of the sales goal. According to CS No. 7, he or she knew that from experience, Plenaxis was a failed drug in June 2004.

99. In May 2005, Praecis ceased marketing Plenaxis.

**ADDITIONAL FACTS DEMONSTRATING SCIENTER**

100. Based on statements made by the Confidential Sources, beyond the direct contact with the sales staff, Defendants had access to reports and other sources of information that if examined, would have revealed that Plenaxis was a “failed drug” from the beginning. According to CS No. 1, all sales representatives accessed an internal Praecis network via remote virtual private network connections. Once connected, sales representatives used web browsers to view Plenaxis sales information. The internal system was called SPIDER. SPIDER tracked all sales, and included such information as total Plenaxis vials sold, vials sold per sales representative, and details of the prescription and the prescribing doctor’s name.

101. According to CS No. 5, Defendants could use SPIDER to compare individuals, regions, or national sales performance. Indeed, it was possible to graph sales performance by week or month and chart the performance of individual sales representatives. Moreover, CS No. 5 stated, if there was good news available for that week, Sherman would urge sales representatives to “check SPIDER” when sending out voicemails to the sales team.

102. In addition to SPIDER, Defendants also participated in weekly regional and national conference calls with the sales staff. As set forth by CS No. 1, because sales representatives worked out of their homes, they would meet via teleconference or in-person meetings with their Regional Managers. After the meetings, evaluations were written and submitted to management. CS No. 1 also spoke to management via telephone, including defendants Malcolm Geffer and Kevin McLaughlin. CS No. 2 stated that sales teams held weekly conference calls. District Managers ran the conference calls. In the calls, the staff discussed Plenaxis sales messaging and sales numbers.

CS No. 2 recalled that although certain large metropolitan areas had some sales success, the drug was an utter failure outside of the cities, especially in conservative areas.

103. In addition to the evaluations to management, CS No. 1 stated that Sherman presented Plenaxis sales forecasts at each meeting. Regional Managers also had hard copy of sales forecasts. Sherman sent weekly voice messages to sales representatives, telling them how many vials of Plenaxis they needed to sell that week and how many vials had been sold the previous week.

104. Through SPIDER, and the conference calls with the sales staff, Defendants, if they had not previously known or recklessly disregarded that information, knew or should have known that Plenaxis could not achieve the forecasted numbers, or indeed bring the Company into profitability in 2006.

**Materially False And Misleading  
Statements Issued During The Class Period**

105. The Class Period commences on November 25, 2003. At that time, Praecis announced that the FDA had approved its lead product, Plenaxis. For safety reasons, Plenaxis was approved with marketing restrictions under 21 CFR 314, Subpart H, and would be available only to physicians who enroll in the PLUS Program. With respect to the Plus Program, the Company stated:

**PLUS Program**

The Plenaxis(TM) risk management program approved by the FDA includes, among other elements:

- Product labeling regarding the risk of immediate-onset systemic allergic reactions and the decreased effectiveness of Plenaxis(TM) in suppressing serum testosterone to castrate levels with continued dosing in some patients;
- An agreement for physicians which must be signed in order to become a prescriber of the drug;

- An agreement for hospital pharmacists confirming their participation in the program and the actions required prior to dispensing the drug;
- A patient information form which patients sign, indicating that they are informed about the risks and benefits of the drug;
- A program for reporting adverse events, including immediate-onset systemic allergic reactions (anaphylaxis, hypotension (lowering of the blood pressure) and/or syncope (fainting)) to the Company and the FDA; and
- Measures to actively monitor and evaluate the program.

106. Commenting on the approval defendant Gefter stated:

We are delighted with the approval, and would like to thank the FDA for diligently working with us to make this drug available for those prostate cancer patients who are most in need. The approval of Plenaxis(TM) represents years of dedication to drug discovery and development at PRAECIS to bring an innovative product to the market and marks an important milestone in our transition to a fully integrated pharmaceutical company. More importantly, this approval will bring a valuable therapy to those patients in the indicated population who have limited or no other treatment options available.

107. Furthermore, defendant Heiden added:

The launch of Plenaxis(TM) will be supported by the PLUS Program, which is designed with the goal of providing the benefits of enhanced safety for patients taking Plenaxis(TM), as well as education and support for prescribing physicians and dispensing hospital pharmacists. The PLUS Program represents an ongoing effort by the FDA and industry to identify and successfully manage the potential risks of new therapies, while ensuring that these important therapies are available to patients who will most benefit from them.

\*\*\*

The PLUS Program highlights that patient safety is our number one priority[.]...With this program in place, we are now able to direct this therapy into the hands of physicians to treat those patients for whom the benefits of Plenaxis(TM) outweigh the potential risks. In addition, we plan to begin working with the FDA to explore other

patient populations which could be appropriately treated with Plenaxis(TM) in the future.

\*\*\*

We are extremely excited about the launch of our first product and the revenue opportunity it represents. We will begin hiring the Plenaxis(TM) sales force immediately, with initial product shipment targeted for early in the first quarter of 2004.

108. According to Garnick, Praecis' Chief Medical officer, who appeared on a conference call with investors and analysts with the Individual Defendants:

In terms of the market size . . . FDA had talked about 5 to 10% of all prostate cancer patients, and that's not inconsistent with some of our forecasts, *as we've said previously given our market share penetration and also our premium pricing assumptions, we've talked about a 15% plus revenue opportunity of the current \$1.2 billion market* and none of that has changed. That's still the case, and again consistent with the numbers that the FDA stated, again, 5 to 10% of the total number of prostate cancer patients in the United States

109. On November 26, 2003, Defendant Gefter appeared on CNBC to tout Plenaxis's approval. In that appearance, Defendant Gefter stated in response to a question that set forth the analysts' estimates of the market for Plenaxis as between \$50 and \$200 million:

the current market for hormonal therapy is actually \$1.2 billion in the United States alone. And that represents the combined hormonal therapies that are available for prostate cancer patients. And we've estimated that our drug would be applicable to treat a large segment of that population. **And we have estimated somewhere north of 15 to 20 to 30 percent of that size market would be available to patients taking our drug.**

110. Unbeknownst to investors, however, the statements described in 105-109, above, were each materially false and misleading when they were made because they failed to disclose and misrepresented the following adverse facts, among others, that: (i) the primary purchasers, urologists, lacked the necessary distribution system to purchase Plenaxis; (ii) Praecis's pricing structure offered



the target physicians (urologists) little opportunity to profit while at the same time substantially increasing the urologists' risk of loss; (iii) the 30 minute monitoring period further decreased urologists' profits, if any, from Plenaxis because during that time a consultation room could not be used by another patient; (iv) Plenaxis's "black box" warning label also significantly increased urologists treatment and malpractice concerns, particularly in light of the fact that the existing competing medications used to treat prostate cancer bore no such warning labels, had been effectively prescribed for fifteen years, and could be prescribed to a much larger group of prostate cancer patients.

111. The forecasts described in ¶¶ 105-109 were each materially false and misleading when they were made because they lacked a reasonable basis in fact and were indeed contradicted by the adverse facts cited in ¶ 110, among others.

112. On January 30, 2004, Praecis announced consolidated financial results for the three months and year ended December 31, 2003. The Company reiterated its objective to obtain profitability driven by sales of Plenaxis by 2006. For the year ended December 31, 2003, the Company's cash utilization was approximately \$51,843,000. The Company's net loss for the three months ended December 31, 2003 was approximately \$16,048,000, or \$0.31 per diluted share, compared to a net loss of approximately \$13,605,000, or \$0.26 per diluted share, for the three months ended December 31, 2002. For the year ended December 31, 2003, net loss was approximately \$55,798,000, or \$1.08 per diluted share, compared to a net loss of approximately \$46,075,000, or \$0.89 per diluted share, for the year ended December 31, 2002. Commenting on these results, defendant Geftter stated:

The past year was one of significant accomplishment for PRAECIS. In November, we achieved our primary goal for 2003 with the receipt of approval from the United States Food and Drug Administration (FDA) to market Plenaxis(TM) in the United States. **This approval marks our transition to a fully integrated pharmaceutical company with capabilities spanning drug discovery, clinical development, manufacturing and commercialization.** The approval of Plenaxis(TM) also validates our scientific approach of using proprietary technologies to maximize the success of selecting drug candidates for development and commercialization, thereby minimizing high rates of failure. These technologies enable our scientists to conduct a battery of tests to determine the most appropriate drug candidates for advancement into clinical development. This approach was utilized in selecting Plenaxis(TM) and Apan, our compound for the treatment of Alzheimer's disease, for development, and we intend to use these technologies when selecting future development candidates. **We believe that the approval of Plenaxis(TM) confirms our team's ability to translate innovative scientific discoveries into commercial reality, effectively and efficiently.** [Emphasis added.]

113. With respect to commercialization of Plenaxis, the Company stated:

With regard to the commercialization efforts for Plenaxis(TM), the Company has begun shipping product to distributors. Since receipt of FDA approval for Plenaxis(TM) in late November 2003, the Company has hired and trained its medical science liaisons and its regional sales managers, and is aggressively hiring and training its estimated 40 field sales representatives. The Company is currently launching a variety of important marketing initiatives and is leveraging its key opinion leader support through a host of educational programs in the United States.

"We are extremely pleased to announce that Plenaxis(TM) is now available through our authorized distributors to physicians and hospital pharmacies enrolled in the Plenaxis(TM) User Safety (PLUS) Program," stated William K. Heiden, PRAECIS' President and Chief Operating Officer. "Our goal is to have 100% of our sales force hired, trained and in the field by early in the second quarter of 2004. With an expected average of 6-8 years of experience, our well-seasoned field force will provide urologists and oncologists with significant insight into this new treatment for advanced symptomatic prostate cancer."

Commenting on the significant impact of this approval on PRAECIS' business, Mr. Heiden continued, **"The approval of Plenaxis(TM) is enabling us to build a commercialization infrastructure that adds tremendous value to our organization.** We can leverage this infrastructure to position ourselves as a partner of choice for commercializing other urology/oncology products, advance our future products and maintain greater control when evaluating partnership opportunities for our clinical stage products."

The Company is continuing to evaluate the potential utility of Plenaxis(TM) in other indications to further exploit its unique mechanism of action. As part of this process, the Company has established several groups of experienced clinical advisors and continues to work closely with these groups of experts to identify indications where the use of Plenaxis(TM) may provide innovative advantages compared to existing therapies. [Emphasis added.]

114. With respect to its 2004 financial guidance, the Company stated:

The Company believes that it has adequate financial resources to achieve profitability by 2006, assuming the successful commercialization of Plenaxis(TM), the timely partnering of clinical programs and continued prudent fiscal management. **During 2004, the Company forecasts sales of Plenaxis(TM) to range from \$10.0 million to \$20.0 million and anticipates the ramp-up of revenues to be heavily weighted toward the second half of the year.** The Company anticipates updating its financial guidance throughout 2004, as it gains a greater insight into Plenaxis(TM)' revenue trajectory.

**With respect to the future prospects for Plenaxis(TM), the market for currently available hormonal therapies to treat prostate cancer is approximately \$1.2 billion in the United States. The Company believes that the long-term revenue opportunity for Plenaxis(TM) may represent 15% or more of this market.** [Emphasis added.]

115. Unbeknownst to investors, however, the statements described in ¶¶112-14, above, were each materially false and misleading when they were made because they failed to disclose and misrepresented the adverse facts set forth in ¶ 110 and the following adverse facts, among others: (i) the training sessions in which it became clear that the only means by which Plenaxis could be

effectively sold were by using unethical and potentially illegal sales tactics; and (ii) that internal sales goals could, under no conditions, meet the forecasts.

116. The forecasts described in ¶¶ 112-14, above were each materially false and misleading when they were made because they lacked a reasonable basis in fact and were indeed contradicted by the adverse facts set forth in ¶¶ 110, 115, among others:

117. On March 15, 2004, Praecis filed its annual report with the SEC on Form 10-K. The Company's annual report was signed by defendant McLaughlin and reaffirmed its previously announced financial results.

118. On March 31, 2004, Praecis announced it had been informed by The Centers for Medicare & Medicaid Services ("CMS") that Plenaxis had qualified for transitional pass-through payment under the Medicare hospital outpatient prospective payment system ("HOPPS"). More specifically, the Company stated:

PRAECIS greatly appreciates the diligent efforts of CMS in reaching this determination in such an expeditious manner for this important new product," stated William K. Heiden, PRAECIS' President and Chief Operating Officer.

\*\*\*

Continuing, Mr. Heiden stated, **"We are especially pleased to receive this news now, as initial interest in Plenaxis(TM) has been very encouraging, with over 1,000 physicians and hospital pharmacies having enrolled in our PLUS (PLenaxis(TM) User Safety) Program to date."** [Emphasis added.]

119. On May 10, 2004, Praecis filed its quarterly report with the SEC on Form 10-Q. The Company's Form 10-Q was signed by defendant McLaughlin and reaffirmed Praecis' previously announced financial results.

120. On April 30, 2004, Praecis provided an update on the commercialization of Plenaxis in the United States and announced consolidated financial results for the three months ended March 31, 2004. The Company's net loss for the three months ended March 31, 2004 was approximately \$15,380,000, or \$0.29 per diluted share, compared to a net loss of approximately \$11,415,000, or \$0.22 per diluted share, for the three months ended March 31, 2003. Cost of goods sold for the three months ended March 31, 2004 was approximately \$1.1 million, \$1.0 million of which was related to a milestone payment due upon the first commercial sale of Plenaxis(TM). Sales and marketing expenses for the three months ended March 31, 2004 increased to approximately \$4.1 million, from approximately \$1.0 million for the corresponding period in 2003, due to the hiring of a sales force and various launch-related activities, including market research, brand development and the creation of initial marketing materials. With respect to the commercialization of Plenaxis, the Company stated:

In late January 2004, the Company launched its lead product, Plenaxis(TM), for the treatment of a defined subset of advanced symptomatic prostate cancer patients. During the first quarter of 2004, the Company focused on building its commercial infrastructure to support the launch of Plenaxis(TM) in the United States. Field sales representatives were hired and trained during the first quarter and began calling on potential customers to build product awareness, enroll physicians and hospital pharmacies in the Plenaxis(TM) User Safety (PLUS) Program and generate product sales. In order to ensure that Plenaxis(TM) is widely available to prescribing physicians, the Company has established a network of premier specialty distributors, including: Cardinal Health, CuraScript Pharmacy, Inc., McKesson Specialty Distribution Services, Oncology Therapeutics Network and Priority Healthcare Corporation. During the first quarter, these distributors began shipping product to physicians and hospital pharmacies enrolled in the PLUS Program, and patients are now being treated with Plenaxis(TM).

**The Company generated net revenue of approximately \$0.4 million through sales to distributors, representing primarily initial stocking levels. Based upon the first quarter activity, the Company's prior Plenaxis(TM) sales forecast of \$10.0 million to \$20.0 million in revenue for 2004 remains unchanged.**

As of the date of this release, the Company has hired all of its 40 field sales representatives. The initial impact of the Plenaxis(TM) sales force can be seen in the large number of physicians who have signed up to become authorized Plenaxis(TM) prescribers by enrolling in the PLUS Program. Currently, approximately 1,900 physicians and hospital pharmacies have enrolled in the PLUS Program. [Emphasis added.]

\*\*\*

121. Commenting on the first quarter results, defendant Geffer stated:

**"During the first quarter of 2004, PRAECIS continued to capitalize on the Plenaxis(TM) commercial opportunity. Although it is early in the Plenaxis(TM) launch, we are encouraged by the feedback from physicians and expect to build sales during the second half of the year as awareness of the product grows among urologists and oncologists. [Emphasis added.]"**

122. Unbeknownst to investors, however, the statements described in 118-121, above, were each materially false and misleading when they were made because they failed to disclose and misrepresented the adverse facts described in ¶¶ 110, 115 as well as the following adverse facts, among others: (i) dismal sales in the Plenaxis launch; (ii) the failure of Praecis "delayed payment" program"; (iii) the failure of Praecis' pricing structure to attract customers; (iii) the significant returns of Plenaxis from physicians; (iv) the anger caused by distributor charge backs; (v) the instructions to "work the gray area" of the indications to sell Plenaxis; (vi) the instructions to sell Plenaxis for use by patients with "mild" AUA scores in direct contradiction to the FDA restrictions;

(vi) the crumbling morale of the sales force which was reflected in mass voluntary terminations and replacement by inferior sales representatives.

123. The forecasts described in ¶¶ 118-121 were each materially false and misleading when they were made because they lacked a reasonable basis in fact and were indeed contradicted by the adverse facts set forth in ¶¶ 110, 115 and 122 above, among others.

124. On May 24, 2004, Praecis provided an update on the commercialization of Plenaxis in the United States and reviewed the Company's research and development programs and its technology platforms.

Plenaxis(TM) was approved by the United States Food and Drug Administration (FDA) in November 2003 for the treatment of a defined subset of advanced symptomatic prostate cancer patients. The Company launched Plenaxis(TM) in late January 2004 and is promoting the product in the United States with its own marketing and sales team. Discussing the progress of the Plenaxis(TM) launch, Mr. Heiden noted the following:

-- The first quarter was dedicated to the hiring and training of the 40 person sales force, and this experienced team is now calling on physicians to educate and build product awareness, enroll physicians and hospital pharmacies in the Plenaxis(TM) User Safety (PLUS) Program and generate product sales.

-- The Company has identified approximately 3,500 target prescribers, whom it believes may represent 80% of the Plenaxis(TM) volume opportunity. As of today, over 2,200 physicians (and hospital pharmacies) have enrolled as authorized prescribers in the PLUS Program, more than half of whom are target prescribers.

-- Various promotional support programs (including professional advertising) have recently been launched following approval by the FDA's Division of Drug Marketing, Advertising, and Communications, several being made available for the first time to physicians at the recent American Urological Association meeting held in San Francisco from May 8-13, 2004.



-- During May 2004, the Company received its first confirmation that several regional Medicare carriers have already issued physician reimbursement for the in-office administration of Plenaxis(TM) and expects confirmation regarding reimbursement by the remaining carriers in the coming months. The Company believes that confirmation of carrier-level reimbursement is an important step for physicians considering the use of Plenaxis(TM).

-- The Company is initiating the "Plenaxis(TM) Experience Study," a 2,000 patient clinical study evaluating the commercial use of Plenaxis(TM) in the indicated patient population. The study is an FDA postmarketing Phase 4 commitment which will evaluate the adherence by physicians to the requirements of the PLUS Program. The study will also be utilized to further assess the frequency of immediate-onset systemic allergic reactions.

-- The Company has recently received clearance from the FDA to initiate a Phase 1/2 study evaluating the use of Plenaxis(TM) in androgen-independent prostate cancer patients whose disease has progressed following LHRH agonist therapy. Plenaxis(TM) has been shown to directly suppress follicle stimulating hormone (FSH) secretion, which is believed to be an independent growth stimulant of prostate cancer. Many patients treated with hormonal therapies eventually progress to a stage of androgen-independent prostate cancer, and this study will evaluate the potential benefit of suppressing FSH with Plenaxis(TM) in these patients.

125. Unbeknownst to investors, however, the statements described in ¶ 124, above, were each materially false and misleading when they were made because they failed to disclose and misrepresented the adverse facts in ¶¶ 110, 115 and 122 and further failed to disclose the following adverse facts, among others: (i) that the new "focused message" was an illegal and unethical attempt to downplay the serious risks of prescribing Plenaxis while expanding the class of patients to whom it could be prescribed; and (ii) that the sales force, due to substantial attrition was not nearly sufficiently trained or experienced, its morale was in a shambles; and the Company continued to lose its best and brightest sales representatives.



126. On July 30, 2004, Praecis announced consolidated financial results for the three and six months ended June 30, 2004. The Company's net loss for the three months ended June 30, 2004 was approximately \$14,842,000, or \$0.28 per diluted share, compared to a net loss of approximately \$15,550,000, or \$0.30 per diluted share, for the three months ended June 30, 2003. Total revenues during the second quarter of 2004 were approximately \$673,000, compared to zero for the corresponding period in 2003. Sales of Plenaxis(R) in the second quarter of 2004 were \$645,000. For the six months ended June 30, 2004, net loss was approximately \$30,222,000, or \$0.58 per diluted share, compared to a net loss of approximately \$26,965,000, or \$0.52 per diluted share, for the six months ended June 30, 2003. Total revenues for the first six months of 2004 were approximately \$1,134,000, including approximately \$1,056,000 in sales of Plenaxis(R), compared to zero for the corresponding period in 2003. At June 30, 2004, the Company had cash, cash equivalents and marketable securities of approximately \$111,458,000, compared to approximately \$143,192,000 at December 31, 2003.

127. With respect to Plenaxis, the Company stated:

**Plenaxis(R) Update**

In late January 2004, the Company launched its lead product, Plenaxis(R), for the treatment of a defined subset of advanced symptomatic prostate cancer patients. During the first half of 2004, the Company focused on launching Plenaxis(R) by building a full commercial infrastructure. Included within this build-up was the hiring and training of a field sales force of approximately 40 individuals as well as the establishment of the Plenaxis(R) User Safety (PLUS) Program. Physicians who intend to prescribe Plenaxis(R) must first enroll in the PLUS Program. All of the field force has been hired, trained and is now calling on physicians and, as of today, the Company has enrolled approximately 3,000 physicians in the PLUS Program, with more than 10% having already purchased Plenaxis(R).

**“Given our success in enrolling a large number of physicians in our PLUS Program, we have begun to shift our focus,”** stated William K. Heiden, the Company’s President and Chief Operating Officer. **“While educating new physicians and enrolling them in the PLUS Program will be important to the long-term success of Plenaxis(R), our current efforts in the field are focused principally towards assisting PLUS-enrolled physicians to take the next step and become Plenaxis(R) prescribers. We have seen evidence of the success of this strategy in a trend of increasing weekly sales which began in the latter portion of the second quarter. We expect to see Plenaxis(R) sales continue to build quarter on quarter over the course of the year.”**

Longer-term, the Company continues to believe that the revenue opportunity for Plenaxis(R) may represent 15% or more of the \$1.2 billion hormone therapy market for prostate cancer in the United States. [Emphasis added.]

128. On August 9, 2004, Praecis filed its quarterly report with the SEC on Form 10-Q. The Company’s Form 10-Q was signed by defendant McLaughlin and reaffirmed Praecis’ previously announced financial results.

129. Unbeknownst to investors, however, the statements described in 126-128, above, were each materially false and misleading when they were made because they failed to disclose and misrepresented the following adverse facts, among others:

130. The forecasts described in ¶¶ 126-128 were each materially false and misleading when they were made because they lacked a reasonable basis in fact and were indeed contradicted by the following adverse facts, among others:

131. On October 26, 2004, Praecis announced consolidated financial results for the three and nine months ended September 30, 2004. The Company’s net loss for the three months ended September 30, 2004 was approximately \$13,954,000, or \$0.27 per diluted share, compared to a net loss of approximately \$12,785,000, or \$0.25 per diluted share, for the three months ended September

30, 2003. Total revenues during the third quarter of 2004 were approximately \$1,074,000, compared to zero for the corresponding period in 2003. Sales of Plenaxis(R) in the third quarter of 2004 were \$1,032,000. The increased net loss for the three months ended September 30, 2004, compared to the three months ended September 30, 2003, was due to a significant increase in sales and marketing expenses resulting from the hiring of the field force and the establishment of the commercial infrastructure to support the launch of Plenaxis(R) in the United States. For the nine months ended September 30, 2004, net loss was approximately \$44,176,000, or \$0.84 per diluted share, compared to a net loss of approximately \$39,750,000, or \$0.77 per diluted share, for the nine months ended September 30, 2003. Total revenues for the first nine months of 2004 were approximately \$2,208,000, including approximately \$2,088,000 in sales of Plenaxis(R), compared to zero for the corresponding period in 2003. Commenting on the results, defendant Geftter stated:

During the past several months, the Company has gained considerable experience in marketing Plenaxis(R), has undergone significant changes to improve its senior management team and has continued to advance its development and discovery technologies. As we look forward, we expect to begin new clinical trials related to our PPI-2458 and Apan clinical development programs. We further expect that our Direct Select(TM) technology platform will continue to expand in its scope and value as we look to partner this unique discovery capability. All of these changes should positively impact our future as a fully integrated biopharmaceutical organization and we are looking forward to a productive fourth quarter and 2005.

132. With respect to Plenaxis, the Company stated:

In late January 2004, the Company launched its lead product, Plenaxis(R), for the treatment of a defined subset of advanced symptomatic prostate cancer patients. During the first half of 2004, the Company focused on launching Plenaxis(R) by building a commercial infrastructure. Included within this build-up was the hiring and training of a field sales force of approximately 40 individuals as well as the establishment of the Plenaxis(R) User

Safety (PLUS) Program. Physicians who intend to prescribe Plenaxis(R) must first enroll in the PLUS Program. As of today, the Company has enrolled approximately 3,400 physicians (and hospital pharmacies) in the PLUS Program, with more than 15% of enrolled physicians having already purchased Plenaxis(R), compared to approximately 10% of enrolled physicians at the end of the second quarter. Approximately half of physicians who have purchased Plenaxis(R) have already become repeat prescribers. Using the experience gained during the first nine months of launch, the Company will now focus on improving its messaging regarding both the unique attributes of Plenaxis(R) and the specific patients for whom Plenaxis(R) is appropriate, with a view to building on this growing base of prescribers.

Commenting on the Company's commercialization efforts, Kevin F. McLaughlin, the Company's recently appointed President and Chief Operating Officer, stated, **"We are encouraged by the growing base of sales to repeat prescribers. This trend suggests that following their first experience with Plenaxis(R), physicians are pleased with the results and thus are continuing to treat existing patients with, and identify new patients for, Plenaxis(R) therapy.** Accordingly, we expect to see Plenaxis(R) sales continue to build quarter on quarter. We recognize that our sales and marketing organization has faced many challenges, both expected and unexpected, in introducing Plenaxis(R) to the marketplace. **These challenges include the need to clearly differentiate, and educate physicians on, the indicated patient population.** We believe our ability to meet these challenges has been substantially enhanced by our recently announced hiring of Michael J. Keavany as Senior Vice President, Sales and Marketing, to lead the Plenaxis(R) commercialization efforts. Mr. Keavany's strong background in marketing specialty products will be invaluable towards meeting our commitment of making Plenaxis(R) a commercial success." [Emphasis added.]

133. Unbeknownst to investors, however, the statements described in ¶¶ 126-132, above, were each materially false and misleading when they were made because they failed to disclose and misrepresented the adverse facts set forth in ¶¶ 110, 115, 122 and 125.

**The Truth Begins To Emerge**

134. On December 6, 2004, Praecis provided an update on the Company's commercialization of Plenaxis in the United States. More specifically, the Company, in its press release stated:

The Company stated that Plenaxis(R) is an important therapy for patients in the indicated population who have limited or no other treatment options available and reported that physician feedback reaffirms that Plenaxis(R) achieves its intended therapeutic goal of providing these patients with a non-surgical option for managing the symptoms of their advanced prostate cancer.

However, as previously reported, since the initial launch of Plenaxis(R), the Company has faced many challenges that have had an adverse impact on the uptake of the product in the market. These challenges have included the need to achieve sales force efficiency, establish more effective messaging to educate physicians about the product's indication and the appropriate patient population, and overcome physician uncertainty and concerns over reimbursement. More specifically, the Company has found that educating physicians about the Plenaxis(R) User Safety (PLUS) Program and the appropriate patient population for Plenaxis(R) has markedly increased the sales cycle and requires a very focused sales message and sales call. In addition, physicians' concerns over obtaining reimbursement coverage for Plenaxis(R) during the initial launch phase have been compounded this quarter by increasing physician uncertainty regarding the impact of changing pharmaceutical reimbursement for 2005 as a result of recent Medicare reform. The impact of these challenges has negatively affected Plenaxis(R) sales, and therefore, the Company now expects sales to decrease from the third to the fourth quarter of 2004. Despite this shortfall, the Company continues to expect to end the year with cash, cash equivalents and marketable securities of at least \$75.0 million.

\*\*\*

The Company believes that its re-launch of Plenaxis(R) will enable it to capitalize on the product's long term potential. During this re-launch period in the U.S. market, and while the Company awaits approval of its marketing application for Plenaxis(R) in Germany (and then additional European countries), **the Company has decided**

**to remove its previous short and long term sales and earnings guidance, and does not currently anticipate providing further guidance until a consistent trend for Plenaxis(R) sales emerges.**

(Emphasis Added.)

135. News of this shocked the market. Shares of Praecis fell \$.56 per share, or 25.8 percent on December 6, 2004, to close at \$1.61 per share.

**Praecis Pharmaceuticals Inc. said Friday it is cutting 60 percent of its 182-person work force and halting U.S. promotion of a prostate cancer treatment and development of a medication for Alzheimer's disease.**

The moves are part of a cost-cutting campaign that Praecis said will refocus its efforts "on its most promising assets." Those include development of an oral compound for treatment of cancer and autoimmune diseases, and technology to aid drug discovery.

**Praecis said it will reduce its work force to 75 employees, with about 100 workers losing their jobs immediately and a smaller number leaving in the coming months.** The company said it will also consider relocating from its headquarters and research building in Waltham to a smaller facility.

136. The company said it is suspending U.S. promotion of its prostate cancer therapy Plenaxis and will work with the Food and Drug Administration to make the drug available to patients already on the therapy. Praecis will continue seeking approval to market the drug in Europe

#### **UNDISCLOSED ADVERSE FACTS**

137. The market for Praecis' securities was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and failures to disclose, Praecis' securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Praecis securities relying upon the integrity of the market price of Praecis' securities and market information relating to Praecis, and have been damaged thereby.

138. During the Class Period, defendants materially misled the investing public, thereby inflating the price of Praecis' securities, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make defendants' statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

139. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by plaintiff and other members of the Class. As described herein, during the Class Period, defendants made or caused to be made a series of materially false or misleading statements about Praecis' business, prospects and operations. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Praecis and its business, prospects and operations, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

#### **ADDITIONAL SCIENTER ALLEGATIONS**

140. As alleged herein, defendants acted with scienter in that defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in



the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Praecis, their control over, and/or receipt and/or modification of Praecis' allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Praecis, participated in the fraudulent scheme alleged herein.

141. Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including the Individual Defendants.

142. As set forth above, the Individual Defendants had access to numerous reports, systems and forecasts that demonstrated the on-going failure of Plenaxis. The Individual Defendants through their access to SPIDER, the conference calls with the sales staff, Regional Manager's evaluations of staff conferences, sales forecasts produced by Jeff Sherman and others, had clear and concise information regarding the failure of Plenaxis to find a market. Defendants, if they had not recklessly disregarded that information, knew or should have known that Plenaxis could not achieve the forecasted numbers, or indeed bring the Company into profitability in 2006

143. During the Class Period and with the Company's stock trading at an inflated price, defendant Gefter sold 600,000 shares for proceeds of \$4,146,000.



### **NO SAFE HARBOR**

144. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as “forward-looking statements” when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Praecis who knew that those statements were false when made.

### **FIRST CLAIM**

#### **Violation Of Section 10(b) Of The Exchange Act Against And Rule 10b-5 Promulgated Thereunder Against All Defendants**

145. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

146. During the Class Period, defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Praecis securities at artificially inflated prices. In furtherance of

this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

147. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Praecis securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

148. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Praecis as specified herein.

149. These defendants employed devices, schemes, and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Praecis value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Praecis and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Praecis securities during the Class Period.

150. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

151. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Praecis operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

152. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Praecis securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Praecis publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the market in which the securities trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by defendants but not disclosed in public statements by defendants during the Class Period, Plaintiff and the other members of the Class acquired Praecis securities during the Class Period at artificially high prices and were damaged thereby.

153. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Praecis was experiencing, which were not disclosed by defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Praecis securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

154. By virtue of the foregoing, defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

155. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

## **SECOND CLAIM**

**Violation Of Section 20(a) Of  
The Exchange Act Against the Individual Defendants**

156. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

157. The Individual Defendants acted as controlling persons of Praecis within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

158. In particular, each of these defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

159. As set forth above, Praecis and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the

Exchange Act. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

**WHEREFORE**, plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action, designating plaintiff as Lead plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

(b) Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: August 1, 2005

/s/ David Pastor

David Pastor (BBO #391000)

**GILMAN AND PASTOR, LLP**

60 State Street

Boston, MA 02109

Telephone: (617) 742-9700

Facsimile: (617) 742-9701

Eric J. Belfi

**MURRAY, FRANK & SAILER LLP**

275 Madison Avenue, Suite 801

New York, New York 10016

Telephone: (212) 682-1818

Facsimile: (212) 682-1892

Michael Goldberg

**GLANCY, BINKOW & GOLDBERG LLP**

1801 Avenue of the Stars, Suite 311

Los Angeles, CA 90067

Phone: (310) 201-9150

Fax: (310) 201-9160

**Attorneys for Plaintiff**